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| 10/662,477 | 09/16/2003 | Josephus H. M. Lange | 01975.0047 | 9637 |

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EXAMINER

CHUNG, SUSANNAH LEE

| | |
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| ART UNIT | PAPER NUMBER |
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1626

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,477

Applicant(s)

LANGE ET AL.

Examiner

Susannah Chung

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>9/16/03, 1/12/04, 4/9/04</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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DETAILED ACTION

Claims 2-9 are pending in this application. Claim 1 has been canceled by supplemental amendment filed on September 25, 2006.

Information Disclosure Statement

Applicant's information disclosure statement (IDS), filed on September 16, 2003, January 12, 2004, and April 9, 2004 have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Priority

This application claims the benefit of European Patent Application No. 02078966.5 filed on 09/19/2002, which patents have not been issued as of 10/31/2006. This application names an inventor or inventors named in the prior application. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the above applications was received on 9/16/2003.

Response to Election/Restrictions

Applicant's election *with traverse* of Claims 2-5 drawn to compounds and compositions of formula (I), in the reply filed on 09/25/2006 is acknowledged. The election of species of 5-(4-chlorophenyl)-1-(2,4-dichlorophenyl)-N-(piperidin-1-yl)-1H-1,2,4-triazole-3-carboxamide hydrochloride is also acknowledged. Based upon the election, examiner will begin searching the compound of formula (I), wherein R is 2,4-dichlorophenyl; R1 is 4-chlorophenyl; and R2 and R3 together form the saturated substituent piperidine (piperidin-1-yl).

Applicant's election with traverse of Group I in the reply filed on 09/25/2006 is acknowledged. The traversal is on the ground(s) that (1) multiple independent or distinct

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inventions must be established and (2) that the search and examination of each of these groups would constitute a serious burden on examiner. This is not found persuasive because MPEP 803.02 and cases such as In re Harnish state that the Commissioner (Director) has the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The previous office action indicates that more than one independent and distinct invention is claimed in this application and has restricted (limited) the claimed subject matter accordingly. Thus the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention.

There is a serious burden on examiner to search and classify all of the compounds of claim 2. The variables R, R1, R2, R3, etc... result in vastly different compounds and involve search in different classes and subclasses. For example, R3 can be heterocyclic rings ranging from 5 to 8 members and optionally having O, N, and S. The amount of time it would take to determine the possible moieties would be exorbitant and then to further classify the resulting compounds would cause an extreme burden on examiner.

R and R₁ have the meanings as given in claim 1, R and R₁ independently represent a phenyl, naphthyl, thienyl, pyridyl, pyrimidyl, pyrazinyl, pyridazinyl or triazinyl group, which groups are optionally substituted with 1-4 substituents X, which can be the same or different, and are chosen from branched and unbranched (C₁₋₃)-alkyl and alkoxy, hydroxy, halogen, trifluoromethyl, trifluoromethylthio, trifluoromethoxy, nitro, amino, mono- and dialkyl (C₁₋₂)-amino, mono- and dialkyl (C₁₋₂)-amido, (C₁₋₃)-

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alkoxycarbonyl, trifluoromethylsulfonyl, sulfamoyl, (C₁₋₃)-alkylsulfonyl, carboxyl, cyano, carbamoyl, (C₁₋₃)-dialkylaminosulfonyl, (C₁₋₃)-monoalkylamino-sulfonyl and acetyl groups;

R₂ represents a hydrogen atom or a branched or unbranched C₁₋₈ alkyl group;

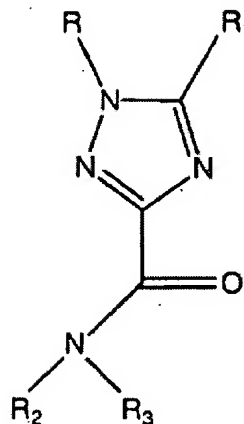
R₃ represents branched or unbranched, C₂₋₈ alkoxy, C₃₋₈ cycloalkyl, C₅₋₁₀ bicycloalkyl, C₆₋₁₀ tricycloalkyl, C₄₋₈ alkenyl, C₅₋₈ cycloalkenyl, which groups may optionally contain one or more heteroatoms chosen from the group (O, N, S) O, N, and S, which ~~groups may optionally be~~ heteroatoms are optionally substituted with a hydroxy group or 1-3 fluoro atoms, or R₃ represents a C₃₋₈ trifluoroalkyl or C₂₋₈ fluoroalkyl group, or R₃ represents a benzyl or phenethyl group, which aromatic rings ~~may be~~ are optionally substituted with 1-4 substituents X, wherein X has the meaning as given in ~~claim 1 above~~, or R₃ represents a 3-pyridyl, 4-pyridyl, pyrimidyl, pyrazinyl, pyridazinyl, triazinyl or thienyl group, which heteroaromatic rings ~~may be~~ are optionally substituted with ~~1-2~~ 1 or 2 substituents X, wherein X has the meaning as given in ~~claim 1 above~~, or

Therefore, in view of the claims having more than one independent or distinct inventions and that search and examination of each of the groups would pose a serious burden on examiner, the claims maybe restricted under 35 USC 121. Accordingly, restriction is proper and is maintained.

Scope of Elected Subject Matter

The scope of the invention of the elected subject matter is as follows:

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Claims 2-5 drawn to compounds of formula (I), , wherein

R is 2,4-dichlorophenyl;

R₁ is 4-chlorophenyl; and

R₂ and R₃ together form saturated piperidine (piperidin-1-yl).

Based upon Applicant's election, Examiner will search various subclasses of classes 514 and 548. All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.)

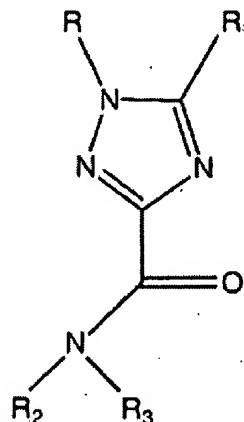
Scope of Withdrawn Subject Matter

Claims 6-9 have been withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected subject matter. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require

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separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the invention of the non-elected subject matter is as follows:



Claims 2-5 drawn to compounds of formula (I), , wherein

R and R1 is

thienyl, pyridyl, pyrimidyl, pyrazinyl, pyridazinyl or triazinyl
group, which groups are optionally substituted with 1-4 substituents X, which can be the
same or different, and are chosen from branched and unbranched (C₁₋₃)-alkyl and
alkoxy, hydroxy, halogen, trifluoromethyl, trifluoromethylthio, trifluoromethoxy, nitro,
amino, mono- and dialkyl (C₁₋₂)-amino, mono- and dialkyl (C₁₋₂)-amido, (C₁₋₃)-
alkoxycarbonyl, trifluoromethylsulfonyl, sulfamoyl, (C₁₋₃)-alkylsulfonyl, carboxyl, cyano,
carbamoyl, (C₁₋₃)-dialkylaminosulfonyl, (C₁₋₃)-monoalkylamino-sulfonyl and acetyl
groups;

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R₂ represents a hydrogen atom or a branched or unbranched C₁₋₈ alkyl group;

R₃ represents branched or unbranched, C₂₋₈ alkoxy, C₃₋₈ cycloalkyl, C₅₋₁₀ bicycloalkyl, C₆₋₁₀ tricycloalkyl, C₄₋₈ alkenyl, C₅₋₈ cycloalkenyl, which groups may optionally contain one or more heteroatoms chosen from the group (O, N, S) O, N, and S, which ~~groups may optionally be~~ heteroatoms are optionally substituted with a hydroxy group or 1-3 fluoro atoms, or R₃ represents a C₃₋₈ trifluoroalkyl or C₂₋₈ fluoroalkyl group, or R₃ represents a benzyl or phenethyl group, which aromatic rings ~~may be~~ are optionally substituted with 1-4 substituents X, wherein X has the meaning as given in ~~claim 1 above~~, or R₃ represents a 3-pyridyl, 4-pyridyl, pyrimidyl, pyrazinyl, pyridazinyl, triazinyl or thienyl group, which heteroaromatic rings ~~may be~~ are optionally substituted with ~~1-2~~ 1 or 2 substituents X, wherein X has the meaning as given in ~~claim 1 above~~, or

R₂ and R₃ together is anything but saturated piperidine (piperidin-1-yl).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Search Expanded

The elected species appears allowable at this point in examination. The search will be expanded, wherein R and R₁ are optionally substituted phenyl; R₂ is hydrogen and R₃ is benzyl.

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Claim Rejections - 35 USC § 102

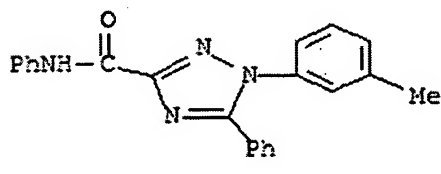
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki, et al (U.S. Pat. No. 4,795,484 (1989)).

Applicants claims relate to compound of Formula (I) in claim 1. Aoki discloses compounds that anticipate the instantly claimed genus wherein: R and R1 are optionally substituted phenyl; R2 is hydrogen; and R3 is benzyl. (see Aoki, claim 1, column 12, CAS RN 88838-62-4, 5-diphenyl-1-(3-methylphenyl)-N-1H-1,2,4-triazole-3-carboxamide,

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described

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in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claims.

The specification failed to define the terms “prodrug” so as to determine the structure of the compounds that are included and/or excluded by these terms.

“Prodrug” is indefinite. There is no definition in the specification describing what the product of the compound of formula (I) is.

A proper definition of “prodrug” will address how the compounds are converted into the prodrug. In addition, the definition should also address the following exemplary list:

- How were the prodrugs prepared? Ex. Prepared by modifying one of the functional groups. Then list the relevant functional groups.
- What compounds are included in the definition of prodrug? Ex. Prodrugs include compounds of Formula I wherein a hydroxyl group is bonded to any group that may be cleaved in vivo to regenerate the free hydroxyl group respectively.
- How are the prodrugs be metabolized? Ex. Prodrug can be metabolized before absorption.
- How are the prodrugs utilized? Ex. Prodrug may be utilized to improve bioavailability.
- What references were used? List the references.

Applicant can overcome this rejection by revising the definitions in the specification. However, applicants should note that the introduction of new subject matter into the specification will raise the issue of new matter. Alternatively, applicant is invited to point out where the definitions are in the original specification, claims or drawings or applicant may amend the claims and delete the term “prodrug.”

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Telephone Inquiry

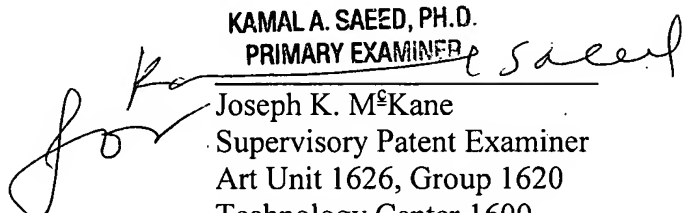
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098.

The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Chung
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Technology Center 1600

Date: 1 November 2006